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~~49~~. The device of claim 1 wherein the detent and groove engagement is dimensioned and configured to releasably maintain the device in the sharpened configuration prior to its movement to the blunted configuration.

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~~50~~. The method of claim ~~31~~ further comprising mounting the self-blunting needle device on a syringe.

## REMARKS

Claims 1, 2, 6, 7, 9, 31, 33-35 and 39-41 are in prosecution and stand rejected under 35 U.S.C. §102.

The Examiner rejected claim 41 under 35 USC 112, second paragraph, for the reasons noted. Claim 41 has been amended to correct this. The remaining claims stand rejected under 35 U.S.C. §102.

Response to Rejections-35 U.S.C. §102(b) based on Aniuk et al

The Examiner rejected claims 1, 2, 6, 31, 33 to 35, 39 and 40 stand rejected under 35 USC 102(b) as being anticipated by Aniuk et al (U.S. Patent 4,911,691) for the reasons noted in paragraph 5 of the office action.

Aniuk et al disclose in Figure 2 through-the-needle catheter assembly. The needle 12 cannula 22 carries a luer fitting 24 and the catheter 20 carries a luer fitting 28 for connection to an intravenous line. In use, after the needle 22 is inserted in the body, the catheter 20 is inserted and the needle 22 is then removed. See discussion in column 7, lines 38 to 66.

The luer fitting 28 on the catheter appears to fit into luer fitting 24 on the needle, but there is no mention of any device to secure the two luer fittings together.

Claim 1 has been amended to recite a new element (e) "a detent and groove engagement between the external component and the internal component configured to inhibit movement from the blunting configuration to the sharpened configuration". Support for this matter is found in the specification in Figure 4 and on page 9, line 24-27, page 21, lines 24 to 26, page 11, lines 20 to 26 and page 18, line 30, to page 19, line 4. As described therein, the detent and groove engagement protects the user by helping to maintain the device in a blunted configuration. Thus, penetration by the sharp needle tip is prevented even when the tip of the device is accidentally pressed against the user's skin. No such engagement between the blunt catheter 20

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and the needle cannula 22 or the luer fittings thereon is shown by Aniuk et al. Therefore, claim 1 and claims 2 and 6 dependent therefrom are clearly distinguishable over the Aniuk et al patent. The rejection under 35 U.S.C. §102 is therefore respectfully traversed.

Furthermore, the Aniuk et al reference provides no suggestion or motive towards adapting the device shown therein to inhibit movement from a blunted configuration to a sharpened configuration or to include a detent and groove engagement as now required by claim 1. Accordingly, claim 1 and claims 2 and 6 dependent therefrom are not only novel, they are patentably distinct in view of Aniuk et al.

Claim 31 has been amended so that it now describes the assembly of self-blunting needle for a syringe. The method now defined by claim 31 is clearly distinct from the disclosure of the Aniuk patent, which shows only the insertion of a catheter to which an intravenous line is attached into an introducer needle. The needle carries a hub which has a guide surface as required by claim 31, but nowhere does Aniuk et al teach or suggest that the catheter assembly shown therein could be mounted on a syringe or that a guide surface such as the one shown on the needle in Aniuk's Figure 2 could be provided on a needle for a syringe. By specifying that the needle device is for a syringe, the claim distinguishes the recited method from the use of a through-the-needle catheter as shown by Aniuk et al, because a person of ordinary skill in the art would recognize that the assembly of a needle for a syringe is not analogous to the assembly of a catheter assembly as shown by Aniuk et al. A syringe needle device is typically not assembled by the user of the syringe, but by a manufacturer, and a syringe needle is assembled before the needle is inserted into a patient. In contrast, Aniuk et al specifically teaches that the catheter and needle assembly described therein is assembled by the user, while the needle is in the patient. Such a device and method of assembly is not analogous to the assembly of a needle device for syringes. Therefore, the prior art provides no teaching or suggestion for the method of assembling a needle device for a syringe as now defined in claim 31.

New claim 50 (support for which can be found in Figure 7 of the subject application and the text pertaining thereto at page 20, line 27 et seq.), adds the further method step of securing the assembled self-blunting needle device onto the syringe. For the reasons set forth above, the prior art nowhere teaches or suggests assembling a self-blunting needle device for a syringe as described in claim 31 and then securing the device onto a syringe barrel as recited in claim 50. For these reasons, claim 31 and claims 33, 34 and 50 dependent therefrom are patentably distinct from the prior art.

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Claim 34 has been amended to provide for consistent use in terminology.

Claim 35 further defines the method of claim 31 by specifying that in assembling the device, the external component, i.e., the needle cannula, contacts a guide surface as well as the internal component, i.e., the blunting member. Claim 39 has been amended so that it now similarly describes a method involving the use a guide member having guide surfaces at both ends, to facilitate the mounting of the needle cannula in one end and the introduction of the blunting member into the needle cannula from the other end. No such arrangement is shown or suggested in the Aniuk et al patent. All of the luer fittings to which the Examiner refers for disclosure of a guide surface in Aniuk et al provide only a guide surface to guide an internal member into an external member. In particular, nowhere does Aniuk et al indicate that needle hub 24 has a guide surface at both ends to facilitate mounting needle 22 into hub 24. Furthermore, nowhere is there a suggestion that both the needle cannula (an external member) and the blunting member therein be brought into contact with guide surfaces in order to assemble a single device. Accordingly, claim 35 and claim 39 both clearly define embodiments which are novel and nonobvious in view of the cited reference.

Response to Rejections-35 U.S.C. §102(b) based on Sahi et al

Claims 1, 7, 9, 31, 39 and 40 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sahi et al, U.S. Patent 4,828,547.

The Sahi et al patent discloses a self-blunting needle assembly for a syringe. The needle assembly comprises a needle cannula mounted on a hub and a blunting member movably disposed within the needle cannula. In each embodiment the opening of the needle cannula is surrounded by a flat wall having a perpendicular orientation to the axis of the needle. Accordingly, there is no guide surface extending axially towards the through-bore of the needle as recited in part (d) of claim 1. As a result, in order to assemble the device shown in Sahi et al, the blunting probe 40 must be precisely aligned with the opening of the needle cannula.

In the present invention, claim 1, item (d), recites a guide surface which leads axially towards the needle through-bore. In this embodiment of Figure 1A, such a guide surface is provided by ferrule 22 as seen in Figure 1A. The guide surface facilitates assembly of the device because it is configured to lead the blunting member axially towards the through-bore of the needle cannula 18b. There is clearly no structure in the Sahi et al patent that functions in this manner and no suggestion therein towards providing such a structure. Claim 1 and the

claims dependent therefrom are thus clearly distinguishable from Sahi. Furthermore, these claims are non-obvious because nowhere does Sahi suggest any device for guiding the blunting member into the needle.

Claim 31 is directed at the method of assembling a needle device for a syringe and calls for advancing the blunting member into contact with a guide surface which leads axially to the through-bore. This is not shown or suggested by Sahi et al for the reasons set forth above regarding claim 1.

Amended claim 39 defines a method which calls for the use of two guide surfaces, and this claim is patentably distinguishable from Sahi et al for the same reason as claims 1 and 31 and further because Sahi et al nowhere suggests the use of a guide surface for mounting the external component in its hub.

Claim 40 has been cancelled.

Newly Added Claims

New claim 49 states that the detent and groove engagement is configured to releasably maintain the device in the sharpened configuration. Support for this feature can be found in the application at, e.g., page 18, line 30 through page 19, line 14. This claim is allowable at least because it depends from claim 1, which is patentably distinct from the cited references for the reasons set forth above.

New claim 50 is discussed above in the response to the rejection of claims over the Aniuk et al Patent.

Each of the stated ground of rejection have been addressed or traversed. Reexamination and reconsideration of the claims is therefore respectfully requested.

Respectfully submitted,

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